REMARKS

By this paper, dependent claim 24 has been amended to correct dependency. Claims 14-24 remain pending.

In the outstanding Office action dated December 3, 2004, claims 14-24 were rejected under 35 U.S.C. § 102(e) or in the alternative under 35 U.S.C. § 103(a) in view of Mathis (6,129,755). In rejecting the claims, the Examiner stated that the nitinol stent 50 of Mathis "comprises from 50.5%-60% Ni and balance of titanium and the austenite finish temperature of Af of about 24-37 degree C (column 8, lines 45-54), therefore, when stent 50 is at least partially deformed and restrained in sheath 40 during a deployment in a body of a patient, because the temperature of the stent 50 inherently is in the temperature range of 24-37° C, stent 50 must be in an austenite state as recited in the claim."

Significantly, at column 9, line 5, the Mathis patent states: "after the stent pattern is cut, the stent is treated and polished using any number of methods well known to those skilled in the art. Lastly, the stent is then cooled until it is completely martensitic, crimped down to its un-expanded diameter and then loaded into the sheath of the delivery apparatus." Therefore, the Mathis patent teaches that the disclosed stent is in a martensitic state when it is at least partially deformed and restrained in sheath 40.

Moreover, it is respectfully submitted that there is nothing in the Mathis patent which supports the Examiner's conclusion that the deformed, martensitic stent of Mathis transforms to an austenitic state when restrained in the sheath and exposed to an environmental temperature in the range of 24°-37° C. In fact, it is respectfully submitted that the restrained stent 40 remains in a martensitic state while constrained in the sheath 40. This is supported by the Mathis patent at column 2, lines 59 et seq. where it describes the shape memory characteristics of alloys such as nitinol. Notably, Mathis states: "Subsequent heating of the deformed martensite phase to a

temperature above the martensite to austenite transformation temperature causes the deformed martensite phase to transform to the austenite phase and during this phase transformation the metal reverts back to its original shape if unrestrained. If restrained, the metal will remain martensitic until the restraint is removed." Accordingly, it is respectfully submitted that it follows that while restrained in sheath 40 the Mathis stent must be martensitic even at an elevated temperature and thus, will be in a martensitic state when in the "at least partially deformed configuration."

Therefore, since independent claim 14 and each of its dependent claims recite a medical device and delivery system including a shape memory alloy element being in an austenitic state when it is in an at least partially deformed configuration, each of the pending claims recite subject matter which is distinguishable from the cited Mathis patent. Accordingly, it is respectfully submitted that each of the pending claims define patentable subject matter.

CONCLUSION

Applicant has attempted to completely respond to the rejections set forth in the outstanding Office action. In view of the above amendments and remarks, Applicant respectfully requests that the application be reconsidered, the claims allowed and the application passed to issue.

Respectfully submitted,

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